

## REMARKS

Claims 1-14 and 16-33 are currently pending in the application. Claims 1 and 30 have been amended to clarify the invention.

Claims 2, 4-14, 16-29 and 33 were withdrawn from consideration by the Examiner as not being readable upon Species III. Applicants respectfully disagree with the Examiner about the withdrawal of these claims. Applicants believe that in addition to claims 1, 3, and 30-32, at least claims 4, 5, 7, 10-13, 18, 20, 23-26, 28 and 33 read on Species III and they should not have been withdrawn by the Examiner. Attached is a replacement drawing sheet for Figure 15G showing the cardiac catheter 126 and flexible rod 348 in relation to the gripper/fastener applicator. No new matter has been added. This drawing change is provided merely to illustrate the catheter and gripper/fastener applicator together, the support of which is clearly provided on at least page 19, lines 28-29 (gripper 371 is a variation of the embodiment shown in Figures 15A-15F), and on page 20, lines 13-17 of the specification ("Clip 373 includes a hole 393 for the passage of flexible rod 348 to manipulate cap 375 from the proximal end of the cardiac catheter 126. Cap 375 also includes an anchor 395, shown in phantom lines, for the attachment of flexible rod 348."). Hole 393 is moved to an axial position to allow flexible rod 348 to pass therethrough in a manner as described in the specification and similar to Figures 15A-F.

In response to the Examiner's position that claims 4, 5, 7, 10-13, 18, 20, 23-26, 28 and 33 are not readable on Species III, claims 4 and 13 elements are now shown in Figure 15G. With reference to claim 5, see elements 383 and 387 on Figure 15G. For claims 7 and 10, replacement Figure 15G shows that element 371 will fit into catheter 126, and 371 will be in an unconstrained extended position as it is removed from catheter 126. For claims 11 and 12, see Figure 15G and page 19, lines 24-27 of the specification. With reference to claim 18, replacement Figure 15G shows shaft 346, cap 375, gripper 371, flexible rod 348, and arms 377, 379. With respect to claims 20 and 23-26, see pivot 381 on Figure 15G and page 18, lines 1-7 and page 19, lines 32-page 20, line 1 of the specification. For claim 28, see Figure 15G and page 20, lines 28-30 of the specification. With reference to claim 33, see elements 371 and 348 in Figure 15G and page 20, lines 28-30 of the specification.

Thus, it is clear that, based on the specification and the replacement drawing of Figure 15G, claims 4, 5, 7, 10-13, 18, 20, 23-26, 28 and 33 should not have been withdrawn. Further, it is clear that claims 1 and 30 are generic to at least species II and III. Reconsideration and reinstatement of claims 4, 5, 7, 10-13, 18, 20, 23-26, 28 and 33 is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss this further. In addition, Applicants will provide a marked up copy of Figure 15G, if needed.

In paragraph 2 on page 2 of the Office Action, claims 1, 3, and 30-32 are rejected under 35 U.S.C. §102 (b) as being anticipated by Krueger, et al., hereinafter Krueger (U.S. Patent No. 5,578,076). Applicants respectfully traverse the rejections.

Applicants respectfully submit that Krueger does not teach every element of claim 1, and therefore fails to anticipate claim 1. The Applicants set forth in claim 1, a heart valve leaflet fastener comprising at least one pair of arms. The at least one pair of arms is sized and adapted for fastening two adjacent tissue heart valve leaflets. The arms pivot from one orientation to a gripping position with ends of respective paired arms being directed toward each other.

Krueger describes a low profile holder for a mechanical heart valve prosthesis. The Examiner cites a pair of arms (16) including curved segments (74) and (76) as describing the elements of claim 1. The Examiner further asserts that the arms of Krueger would have been capable of performing the intended use as claimed, namely that the pair of arms are sized and adapted for fastening two adjacent heart valve leaflets. Applicants respectfully disagree with this assertion and note that intended use recitations and other types of functional language cannot be entirely disregarded.

The Examiner notes that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Claim 1 recites a pair of arms, "...the pair being sized and adapted for fastening two adjacent tissue heart valve leaflets." The "pair being sized" language of claim 1 clearly presents a structural difference between the invention of claim 1 and the arms of Krueger. In contrast to the present invention, the arms 16 of Krueger are coupled to a heart valve holder 14 to hold

a mechanical prosthetic heart valve 12, not tissue heart valve leaflets. As illustrated in FIG. 1, the arms 16 are sized only to grasp holder 14, and in fact are not even sized to grasp prosthetic leaflets 24 and 26. The arms 16 are clearly not sized to even fit within valve orifice 18. Thus, there is a clear structural difference between claim 1 and the holder of Krueger. Claim 1 is neither taught nor suggested by Krueger.

Furthermore, the arms 16 of Krueger are simply not adapted for fastening two adjacent tissue heart valve leaflets. The Examiner maintains that the arms of Krueger are capable of fastening leaflets. However, arms 16 grasp heart valve holder 14, which in turn holds a mechanical heart valve prosthesis. There is simply no teaching or suggestion for using arms 16 to fasten tissue heart valve leaflets. Additionally, the Examiner has provided no objective evidence that the pair of arms 16 of Krueger is even capable of fastening adjacent tissue heart valve leaflets together. Only a conclusory statement related to the claim language is provided. Krueger simply does not teach or suggest a pair of arms being adapted for fastening two adjacent tissue heart valve leaflets.

It is also submitted that a claim preamble must be read in the context of the entire claim (see MPEP 2111.02). In claim 1, the preamble reads, "A heart valve leaflet fastener." This preamble limits both the structure and use of the invention recited therein, since the fastener includes arms sized and adapted for fastening adjacent tissue heart valve leaflets. As discussed in the background of the specification, a bow-tie repair procedure for a tissue heart valve can be used as an alternative to replacement of the tissue heart valve with a mechanical prosthetic valve, as described in Krueger. The heart valve leaflet fastener of claim 1 can be used in a bow-tie repair, which is fundamentally different than the mechanical heart valve replacement discussed by Krueger. As a result, it is submitted that claim 1 is allowable over Krueger and applicants request withdrawal of the rejection to claim 1.

Applicants also submit that Krueger does not teach every element of claim 30 and therefore fails to anticipate claim 30. Independent claim 30 recites a fastening member comprising a cap and a gripper. The gripper is configured to grip a tissue heart valve and comprises a plurality of arms radiating from a pivot with each arm having a

spike. The pivot is inserted within an opening in the cap to lock the arms in a collapsed gripping position.

In FIG. 18, Krueger illustrates a hanger 366 with legs 374 having associated tabs 376. Tabs 376 engage a heart valve holder 300. An opening in hanger 366 allows legs 374 to pivot about a point 372 based on pressure that is placed at points 370 proximate the opening. The Examiner asserts that pivot 372 is inserted into an opening in a cap. However, pivot 372 clearly forms part of the opening, and is thus not inserted within the opening to lock the arms as recited in claim 30. Furthermore, the opening of hanger 366 is not part of a cap that locks the legs 374 in a collapsed gripping position. Instead, as described in column 6, lines 46-51, a separate locking member, in this case a bar extending between points 370, is used to lock legs 374. Thus, Krueger does not teach every element of claim 30 and withdrawal of the rejection to claim 30 is requested.

Applicants respectfully request withdrawal of the rejection of claims 1, 3, and 30-32 under 35 U.S.C. §102 (b) as being anticipated by Krueger, et al.

In view of the reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (612) 334-3222.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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